K110051

FEB - 2 2012

Greatbatch Medical

510(k) Summary

1.0 Applicant Information

Applicant:	Greatbatch Medical
Submitter:	Greatbatch Medical 2300 Berkshire Lane North Minneapolis, MN 55441 (763) 951-8181 (Phone) (763) 559-0148 (Fax)
Contact Person:	Sara Bakker
Date Prepared:	January 5, 2011 *(modified August 28, 2011)*

2.0 Device Information

Trade Name:	RadialSource™ Transradial Access Kit
Common Name:	Sheath Introducer
Classification Name:	Introducer, Catheter
Product Code:	DYB
Regulation:	Class II 21 CFR 870.1340
Classification Panel:	Cardiovascular
Predicates:	Terumo Glidesheath (K082644) Cordis Avanti Trans-Radial Kit (K962746)

3.0 Device Description

The RadialSource™ Transradial Access (TRA) Kit consists of a catheter sheath introducer (CSI), a vessel dilator, a mini-guidewire, and an IV catheter (consisting of an IV cannula and a needle). The CSI is intended to facilitate percutaneous introduction of intravascular devices in arterial or venous procedures through, but not limited to, a radial approach. The vessel dilator and mini-guidewire are used in conjunction with the CSI to gain access to the vasculature. The CSI and vessel dilator contain a lubricious coating intended to reduce friction during insertion

into the vessel. The CSI contains a hemostasis valve at the proximal end which minimizes blood loss and air intake to the vasculature. A sideport infusion line extends from the CSI proximal hub and terminates at a 3-way stopcock with a standard luer fitting for flushing/infusion. The CSI and dilator contain radiopaque material for visualization under fluoroscopy.

4.0 Indications for Use

The RadialSource Catheter Sheath Introducer is indicated for use in arterial or venous procedures requiring percutaneous introduction of intravascular devices.

5.0 Predicate Device Comparison / Technological Characteristics

The RadialSource™ Transradial Access Kit has similar indications for use as the market cleared Cordis Avanti™ Trans-Radial Sheath Introducer Kit and Terumo GlideSheath™. Like the predicates, the RadialSource Transradial Access Kit includes a guidewire, IV catheter/needle vessel dilator and valved introducer intended to gain access and provide percutaneous introduction of catheters and intravascular devices. Terumo GlideSheath and RadialSource are indicated for both arterial and venous procedures; Avanti is indicated for arterial only. The RadialSource Transradial Access Kit shares similar principles of operation and technological characteristics as the predicates. RadialSource is available in similar French sizes but provides a smaller sheath length on the lower end of its sheath length offering. RadialSource also provides a smaller diameter guidewire offering. Performance (bench) testing and biocompatibility testing were performed to demonstrate that the proposed device performs as intended and does not raise new questions of safety or efficacy compared to the predicate devices.

6.0 Summary of Testing

The RadialSource Transradial Access Kit passed all verification specification criteria for dimensional, strength, functional, packaging, sterilization, biocompatibility and shelf life tests. Test results confirm that the device performs as intended without raising new questions of safety and efficacy when compared to the predicate devices. Given the similar technological characteristics and principles of operation of the RadialSource™ Transradial Access Kit as compared to the predicate devices, it was determined that no pre-clinical (animal) or clinical study was necessary. The following non-clinical tests were performed for the RadialSource Transradial Access Kit:

- Biocompatibility testing per ISO 10993-1
  - Cytotoxicity
  - Sensitization
  - ISO Irritation/Intracutaneous Reactivity
  - Acute Systemic Toxicity
  - Materials Mediated Rabbit Pyrogen
  - Bacterial Mutagenicity Test
  - *In Vitro* Chromosome Aberration Assay
  - *In Vitro* Mouse Lymphoma Assay
  - Hemolysis Test

    - Partial Thromboplastin Time
    - Platelet and Leukocyte counts
    - Complement Activation – C3a and SC5b-9
    - Thrombosis (*In-vivo*) 2 dog (4-hour contact)
- USP Physicochemical testing
- Sterilization testing
- Shelf Life

- Performance – Bench:
    - Visual
    - Dimensional
    - Functional:
        - Valve Hemostasis
        - Sheath Hemostasis
        - Sheath/Dilator Compatibility
        - Insertion/Retraction Force
        - Sheath/Dilator Retention
        - Kink
        - Tensile Strength
        - Dilator Luer Taper
        - Guidewire Fracture
        - Guidewire Flex
        - Guidewire Strength of Core Wire to Coil
        - Packaging Seal Strength/Integrity

7.0 Statement of Equivalence

The RadialSource™ Transradial Access Kit has similar indications for use, principles of operation, and technological characteristics as the identified predicates. Based on these similarities, in addition to the results from safety and performance testing, RadialSource™ Transradial Access Kit is considered substantially equivalent to the Terumo Glidesheath™ (K082644) and Cordis Avanti™ Trans-Radial Sheath Introducer Kit (K962746).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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Greatbatch Medical
c/o Ms. Sara Bakker
Senior Regulatory Affairs Specialist
2300 Berkshire Lane N
Minneapolis, MN 55441

Re: K110051
Trade Name: RadialSource Transradial Access Kit
Regulation Number: 21 CFR 870.1340
Regulation Name: Introducer, Catheter
Regulatory Class: Class II
Product Code: DYB
Dated: January 26, 2012
Received: January 27, 2012

Dear Ms. Bakker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K110051

Device Name: RadialSource Transradial Access Kit

Indications for Use:

The RadialSource Catheter Sheath Introducer is indicated for use in arterial or venous procedures requiring percutaneous introduction of intravascular devices.

Prescription Use X AND/OR Over-The-Counter Use_____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

M A Hillebrenner

(Division Sign-Off)
Division of Cardiovascular Devices

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